## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant** 

: Keiji SAKAMOTO et al.

Confirmation No.: 9933

Group Art Unit: Unknown

Appl. No

: 10/573,973

(National Stage of PCT/JP04/14768)

Examiner: Unknown

I.A. Filed

: September 30, 2004

For

: STABLE VITAMIN B6 DERIVATIVE

## INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop <u>AMENDMENT</u>
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, Applicants hereby bring to the attention of the Examiner the following information, which includes information cited in the International Search Report for International Application PCT/JP2004/014768, as well as information cited and discussed in the specification of the above-referenced application.

Applicants note that the International Search Report, in English and Japanese, and the Written Opinion, in Japanese, were filed with the national stage filing of this application on March 30, 2006. Applicants provide herewith an English language version of the International Preliminary Report on Patentability.

The following information is cited in the International Search Report for PCT/JP2004/014768, of which the present application is the National Stage:

- (1) Vinh Pham et al., "Design and Synthesis of Novel Pyridoxine 5'Phosphonates as potential Antiischemic Agents", J. Med. Chem., Vol. 46, pp. 3680-3687, 2003;
- (2) JP 2002-265368 A, September 18, 2002, including an English abstract;

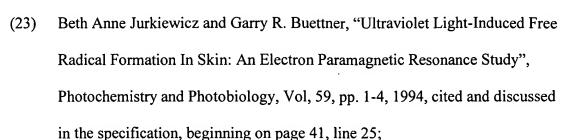
  Applicants note that this document is cited and discussed in the present application, beginning on page 1, line 26;
- (3) WO 02/72039 A2, September 19, 2002, which is an English language family member of document (2).

The following documents are cited and discussed in the specification of the present application:

- (4) Koichi Ogata et al., "Studies on Transglycosidation to Vitamin B6 by Microorganisms", The Journal of Vitaminology, Vol. 15, pp. 160-166, 1969, cited and discussed in the specification, beginning on page 1, line 22;
- Yukio Suzuki et al., "Enzymatic Preparation of Pyridoxine 4'-and 5'-α-D-Glucosides", Methods in Enzymology, Vol. 280, pp. 66-71, 1997, cited and discussed in the specification, beginning on page 1, line 22;
- (6) JP 2002-265316 A, September 18, 2002, including an English language abstract; this document is cited and disccussed in the specification, beginning on page 1, line 25;
- (7) Fusako Kawai et al., "Properties of Pyridoxine Glucoside", The Journal of Vitaminology, Vol. 17, pp. 121-124, 1971, cited and discussed in the specification, beginning on page 1, line 29;

- (8) Masahide Shiroshi and Akira Hayakawa, "Effects of Sunlight Irradiation on Vitamin B<sub>6</sub> Relating compounds", Vitamins, Vol. 22, pp. 138-141, 1961, cited and discussed in the specification, beginning on page 1, last line;
- (9) JP 07-206664 A, August 8, 1995, including an English language abstract; this document is cited and discussed in the specification, beginning on page 2, line 2;
- (10) Shinichi TAKASAKI and Hiroaki YOSHIDA, Katei-yaku Kenkyu (Home Remedy Research)., Vol. 54, No. 5, pp. 54-58, 1986, cited and discussed in the specification, beginning on page 2, line 8;
- (11) JP 05-17355 A, January 26, 1993, including an English language abstract; this document is cited and discussed in the specification, beginning on page 2, line 11;
- (12) Fragrance Journal, Vol. 17, No. 3, pp.96-100, 1989, cited and discussed in the specification, beginning on page 2, line 15;
- (13) Protective Groups in Organic Syntheses, John Wiley & Sons, Inc., 1999, cited and discussed in the specification, beginning on page 9, line 8;
- (14) Handbook of Regents for Organic Synthesis, four volumes in total, John Wiley & Sons, Inc., 1999, cited and discussed in the specification, beginning on page 9, line 9;
- (15) W. Korytnyk and B. Paul, "Acyl Migration and Selective Esterification in Pyridoxol", J. Org. Chem., Vol. 32, pp. 3791-3796, 1967, cited and discussed in the specification, beginning on page 11, line 5;

- (16) Nobuyasu Mizuno and Michiyo Fujimoto, "Hydrolysis of Pyridoxine Monooctanoates", Vitamins, Vol. 49, pp. 395-401, 1975, cited and discussed in the specification, beginning on page 11, line 7;
- (17) Dorothea Heyl et al., "Phosphates of the Vitamin B6 Group I. The Structure of Codecarboxylase", J. Am. Chem. Soc., Vol. 73, pp. 3430-3439, 1951, cited and discussed in the specification, beginning on page 11, line 9;
- Jikken-Kagaku-Koza (Lecture of Experimental chemistry) Vol. 26, 4<sup>th</sup> edition,
   Organic sysnthesis VIII (edited by Chemical Society of Japan, Maruzen,
   1992), cited and discussed in the specification, beginning on page 11, line 30;
- (19) Fundamentals and Experiments of Peptide Synthesis, Maruzen Co., Ltd.,1985, cited and discussed in the specification, beginning on page 14, line 30;
- (20) Stephen P. Coburn et al., "Identification of Pyridoxine 3-Sulfate, Pyridoxal 3-Sulfate, and N-Methylpyridoxine as Major Urinary Metabolites of Vitamin B6 in Domestic Cats", The Journal of Biological Chemistry, Vol. 262, No. 6, pp. 2642-2644, 1987, cited and discussed in the specification, beginning on page 34, line 22;
- Donald L. Bissett et al., "An Animal Model Of Solar-Aged Skin: Historical, Physical, And Visible Changes In UV-Irradiated Hairless Mouse Skin", Photochemistry and Photobiology, Volume: 46, No. 3, pp. 367-378, 1987, cited and discussed in the specification, beginning on page 41, line 1;
- (22) Ernst Graf et al., "Iron-catalyzed Hydroxyl Radical Formation", Journal of Biological Chemistry, Vol. 259, No. 6, pp.3620-3624, 1984, cited in the specification, beginning on page 41, line 26;



The above-listed documents are provided herewith and duly listed on an attached Form PTO-1449. The Examiner is respectfully requested to consider the documents and indicate consideration by initialing the appropriate spaces on the Form PTO-1449.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the listed documents as prior art against any claims in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Applicants note that an Office Action on the merits has not yet issued in the instant application, and thus, no fee is necessary to ensure consideration of this statement. However, if an Office Action has issued and is crossing in the mail with this statement, the Patent and Trademark Office is hereby authorized to charge Deposit Account No. 19-0089 any fee necessary to ensure consideration of the submitted materials.

Should there be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted, Keiji SAKAMOTO et al.

Bruce H. Bernsteit Reg. No. 29,027

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February 22, 2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clarke Place Reston, VA 20191 (703) 716-1191

Stephen M. Roylance Reg. No. 31,296

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	2	English Language Abstract of JP 2002-265368.																
	3	Koichi Ogata et al., "Studies on Transglycosidation to Vitamin B6 by Microorganisms", The Journal of																
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**EXAMINER** 

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pp. 3791-3796, 1967.

**DATE CONSIDERED** 

Handbook of Regents for Organic Synthesis, four volumes in total, John Wiley & Sons, Inc., 1999.

W. Korytnyk and B. Paul, "Acyl Migration and Selective Esterification in Pyridoxol", J. Org. Chem., Vol. 32,

Protective Groups in Organic Syntheses, John Wiley & Sons, Inc., 1999.

<sup>\*</sup>EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Department of Commerce Patent and Trademark Office

Atty. Docket 110 P29617 Application No. 10/573,973

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) Applicant Keiji SAKAMOTO et al.

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	17 Jikken-Kagaku-Koza (Lecture of Experimental chemistry) Vol. 26, 4 <sup>th</sup> edition, Organic sys								nthesis VIII			
		(edited by Chemical Society of Japan, Maruzen, 1992).  18 Fundamentals and Experiments of Peptide Synthesis, Maruzen Co., Ltd., 1985.										
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19 Stephen P. Coburn et al., "Identification of Pyridoxine 3-Sulfate, Pyridoxal								3-Sulfate, and N-				
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		No. 6, pp.3620-3624, 1984.						-				
	22	Beth Anne Jurkiewicz and Garry R. Buettner, "Ultraviolet Light-Induced Free Radical Formation In Skin: An Electron Paramagnetic Resonance Study", Photochemistry and Photobiology, Vol, 59, pp. 1-4, 1994.										
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\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in

conformance and not considered. Include copy of this form with next communication to applicant.